

REMARKS

This application has been carefully reviewed in light of the Official Action mailed January 11, 2007. Claims 1-13 and 58-72 are withdrawn from consideration. Claims 14, 38, 41, and 43 are amended above. Claims 37 and 42 are canceled above without prejudice or disclaimer. Claims 14-36, 38-41, and 43-57 remain pending in this case. Applicant respectfully requests reconsideration of this application and favorable action on all the remaining claims in this case.

In the Official Action, the Examiner rejected claims 14-38 and 41-57 under 35 USC 102(a) & 102(e) as being anticipated by U.S. Patent No. 6,139,646 to Asgharian et al. ("Asgharian"). Amended independent claim 14 requires a composition having:

a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal; and
an *aqueous* otologically acceptable *vehicle, said vehicle including a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal.*

(emphasis added). Amended independent claim 41 requires a two-part composition having:

a first part comprising a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal; and
a second part comprising an *aqueous* otologically acceptable *vehicle, said vehicle including a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal;*
wherein said first and second parts are maintained separate until it is desired to administer said composition to said external ear canal, and wherein said first and second parts are mixed before said administration.

(emphasis added). As is explained in more detail in Examples 1, 2, and 7 of the subject application, such compositions have been shown to be more effective in removing cerumen during *in vitro* testing than conventional cerumenolytics such as 5% sodium bicarbonate solution. In addition, as is explained in more detail in Example 7 of the subject application, compositions including the combination of a cerumenolytically acceptable enzyme and a bicarbonate unexpectedly exhibited a synergistic effect in removing cerumen during *in vitro* testing. See, e.g., subject application page 3, lines 8-

13; page 19, lines 7-23; page 21, line 19 through page 28, line 17 (Examples 1 and 2); page 28, lines 1-9 (definition of “protein component” (280 nm) and “lipid component” (600 nm)); page 32, line 14 through page 34 (Example 7).

Asgharian does not disclose a composition having (a) a cerumenolytically acceptable enzyme **and** (b) an **aqueous** vehicle including a bicarbonate. In contrast, Asgharian discloses a Me-trypsin solution with a borate buffer. *See* Asgharian Example 1. Asgharian also discloses that its Al-trypsin compositions are “initially stabilized in concentrated form” and that its “Al-trypsin concentrate may be formulated as a powder, tablet, or liquid”. Asgharian, column 5, lines 61-63. Asgharian further discloses that its enzyme

tablets may contain effervescing agents such as bicarbonate to expedite dissolution of the tablet into the diluting solution. . . Preferred Al-trypsin tablet compositions comprise sodium bicarbonate, citric acid, PEG-8000, carboxymethyl cellulose and lactose.

Asgharian, column 6, lines 30-37 (emphasis added). For at least these reasons, amended claim 14, and its dependent claims 15-36 and 38-40, and amended claim 41, and its dependent claims 43-57, are novel over Asgharian.

In the Official Action, the Examiner rejected claims 14-18, 21-25, 27, 29, 31, and 34-36 under 35 USC 102(b) as being anticipated by WO 96/40854 to Chowhan et al (“Chowhan”). As shown by ¶ 4 of the Official Action, Chowan does not disclose a composition containing bicarbonate. For at least this reason, amended claim 14, and its dependent claims 15-36 and 38-40, are novel over Chowan.

In the Official Action, the Examiner rejected claims 39-40 under 35 USC 103 as being unpatentable over Asgharian. Claims 39-40 are dependent on amended claim 14. For reasons explained above in connection with the Section 102(a)/102(e) rejection based on Asgharian, Asgharian fails to teach a composition having (a) a cerumenolytically acceptable enzyme **and** (b) an **aqueous** vehicle including a bicarbonate. In addition, Asgharian’s tablet compositions containing bicarbonate as an effervescing agent are not an effective vehicle for the composition of amended claim 14, which assists in the removal of human cerumen **from the external ear canal**. Furthermore, the enzyme tablets of Asgharian include an acid (e.g. citric acid) and a base (e.g. sodium bicarbonate). *See* Asgharian Example 4. If such a tablet is added to

water, sodium citrate and carbon dioxide are produced, and the sodium bicarbonate is consumed in the reaction. Therefore, no bicarbonate is available in the Asgharian tablet to assist in the removal of human cerumen from the external ear canal. For at least these reasons, amended claim 14, and its dependent claims 15-36 and 38-40, are patentable over Asgharian.

In summary, the differences between the subject matter of amended claim 14, amended claim 41, and their respective dependent claims and the Asgharian and Chowan references cited by the Examiner are significant. Given these differences, amended claim 14, amended claim 41, and their respective dependent claims would not have been obvious at the time the inventions were made to a person of ordinary skill in the art. In addition, there is no suggestion in the prior art to modify the teachings of Asgharian and Chowan so as to reach the requirements of amended claims 14 and 41, much less their associated, unexpected, synergistic benefits described hereinabove. Absent such suggestion, any such modification would necessarily be based on the improper hindsight application of the subject applicant's own teachings. For these additional reasons, amended claim 14, and its dependent claims 15-36 and 38-40, and amended claim 41, and its dependent claims 43-57, are patentable over Asgharian and Chowan.

The Commissioner is hereby authorized to charge the following fee amounts required or credit any overpayment associated with the filing of this Amendment to **Deposit Account No. 501051 of Alcon, Inc.:**

- 1) The fee amount of \$1020.00 for the Petition for Extension of Time for three (3) months, from April 11, 2007 to July 11, 2007, to respond to the Official Action, which is being filed concurrently with this Amendment.

The Commissioner is hereby authorized to charge any other amount required for the filing of this Amendment, or credit any overpayment, to **Deposit Account No. 501051 of Alcon, Inc.**

Should the Examiner have any questions regarding this Amendment, please feel free to contact the undersigned attorney at the phone number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "W. David Lee". The signature is fluid and cursive, with the first name "W." and last name "Lee" clearly distinguishable.

W. David Lee
Reg. No. 39,743

Alcon Research, Ltd.
IP Legal TB4-8
6201 South Freeway
Fort Worth, Texas 76134-2099
Tel: 817/568-6029
Fax: 817/551-4610